# **REMARKS**

Docket No.: 30986/42246

### I. The Amendments to the Claims

Claims 18-25 have been amended, and claims 26-35 have been added. Claim 18 has been amended to recite "mg/m²," thereby correcting an obvious typographical error highlighted by the recitation of "mg/m²" for all other measurements disclosed in the application. Claims 19-25 have been amended to clarify the dependent nature of these claims without narrowing the claims. Claims 19, 21, 22, 24, and 25 have been further amended to delete "preferable" features from the claims, which are now the subject of new claims 26-28 and 30-35. New claims 26-35 find support in claims 18-25. No new matter has been added by way of these amendments. Claims 18-35 are currently pending and subject to examination.

### II. The Office Action

The Office rejected claims 18-25 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. The Office further rejected claims 18-23 and 25 under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Patent No. 5,260,282 ("Attstrom") and/or International Patent Publication WO 93/16707 ("O'Mullane"). Claims 18-25 also were rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over O'Mullane and/or Attstrom taken in view of O'Mullane. Reconsideration of these rejections is respectfully requested.

## III. The Rejection Under 35 U.S.C. § 112, Second Paragraph, Is Moot.

Claims 18-25 were rejected under Section 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the invention. The Office contends that claim 18 should read "mg/m²," and the recitation of preferred ranges in claims 19, 21, 24, and 25 render those claims indefinite. The rejection is moot in light of the claim amendments: claim 18 was amended to correct the obvious typographical error and the preferred ranges are now the subject of new claims.

### IV. The Rejection Under 35 U.S.C. § 102(b) Should Be Withdrawn.

Claims 18-20, 22, 23, and 25 were rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Attstrom. Claims 18-23 and 25 were rejected under 35 U.S.C.

§ 102(b) for allegedly being anticipated by O'Mullane. This rejection is traversed for the reasons set forth below.

The cited references anticipate the pending claims *only* if the reference teaches *each and every element* of the pending claims. See, e.g., *Verdegaal Bros. v. Union Oil Co. of CA*, 814 F.2d 628, 631 (Fed. Cir. 1987). Attstrom does not teach every feature of the claimed method for treating xerostomia. The presently claimed method comprises administering a composition comprising a solid, dried, water-soluble or water-dispersible linseed extract. While Attstrom mentions freeze-dried linseed extract, the reference only teaches use of the solid form for storage (Attstrom at, e.g., Example 3). Attstrom discloses administration only of *aqueous* linseed extract to a subject. At column 4, lines 20-25, for example, Attstrom teaches *dissolving* dried linseed extract before use as a saliva substitute (see also, e.g., column 2, lines 65-66, and column 3, lines 28-34). In that Attstrom does not teach each and every feature of the claimed method, the cited reference does not anticipate the subject matter of claims 18-20, 22, 23, and 25.

Likewise, O'Mullane fails to teach each and every feature of the claimed subject matter. O'Mullane generally discloses that linseed mucilage (extract) is a viscous liquid that is useful as an artificial mucus, and that the extract can be dried. However, there is no explicit disclosure in O'Mullane that dried, solid linseed extract (much less freeze-dried or spray-dried solid linseed extract) can be successfully administered *in the treatment of xerostomia*.

In addition, Applicants respectfully submit that the rejection is based on an incorrect assumption regarding adsorption characteristics. The Office asserts that the dried extracts of O'Mullane would inherently have the adsorption characteristics required by the pending claims, i.e., at least 1.2 mg/m². On the contrary, a range of adsorptions could be produced by drying linseed extracts. The Office inappropriately supported this factual assumption by pointing to a figure in Applicants' application, which describes *Applicants' invention*. The Office cited no additional support for its factual assumption. The adsorption values recited in the pending claims are not inherently disclosed in O'Mullane, and, therefore, the reference does not anticipate the pending claims. As such, the rejection of claims 18-23 and 25 under Section 102(b) should be withdrawn.

## V. The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn.

Claims 18 and 23-25 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious in view of O'Mullane. Claims 18-25 also were rejected under 35 U.S.C. § 103(a) for allegedly being obvious in view of Attstrom taken in view of O'Mullane. This rejection is traversed for the reasons set forth below.

One of ordinary skill in the art would not produce the solid, dried linseed extract defined in claim 18, then use the solid, dried linseed extract in a method for treating xerostomia, starting from the O'Mullane disclosure. The solid, dried linseed extract of the inventive method, in particular spray-dried linseed extract, has a surprisingly high adsorption level that could not be predicted from the prior art. As noted above, the subject matter of O'Mullane would not inherently have the adsorption properties required by the pending claims, which properties make the solid, dried linseed extract of the inventive method particularly advantageous in the treatment of xerostomia. The unexpected advantages of the solid, dried linseed extract of the claimed method could not be predicted from the prior art. O'Mullane does not teach or suggest the advantages of having the claimed adsorption properties, nor does the reference teach or suggest the method recited in the claims for measuring the adsorption characteristics. Accordingly, the subject matter of the pending claims cannot be considered as obvious in view of O'Mullane.

Attstrom disclosure does not cure the deficiencies of O'Mullane. As explained above, Attstrom only discloses administration of *aqueous* linseed extract. The reference does not teach or suggest administering solid, dried linseed extract in a method for treating xerostomia. Furthermore, the dried extracts of Attstrom would not inherently have the adsorption characteristics required by the pending claims, i.e., at least 1.2 mg/m². Like O'Mullane, Attstrom fails to teach or suggest the advantages of having the claimed adsorption properties, and fails to teach or suggest the method recited in the claims for measuring the adsorption characteristics. As such, Attstrom suffers from the same deficiency as O'Mullane, which fails to render the claimed subject matter obvious. Accordingly, the subject matter of claims 18-25 cannot be considered as obvious over the combination of O'Mullane and Attstrom, and the rejection under Section 103(a) should be withdrawn.

## VI. Conclusion

In view of the above amendment and remarks, Applicants submit that all outstanding rejections of the claims have been overcome or rendered moot, and the claims are in condition for allowance.

Dated: March 13, 2008

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